Specific Accreditation Criteria

ISO/IEC 17025 Application Document

Life Sciences - Appendix

Applicable to the following activities:

- **Agribusiness;**
- **Environment;**
- **Food & Beverage;**
- **Healthcare, Pharmaceutical & Media Products;**
- **Human Testing for Workplace and/or Community Screening;**
- **Human Pathology.**
  (qualified as detailed in this documents)

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Purpose

In addition to the *ISO/IEC 17025 Standard Application Document* (SAD), this document provides interpretative criteria and recommendations for the application of ISO/IEC 17025 in Life Sciences for both applicant and accredited facilities.

*In exceptional circumstances facilities performing Human Pathology are accredited to ISO./IEC 17025. These exceptional circumstances are:

1) facilities performing routine pathology testing in the context of support of clinical trials where no diagnostic patients' results are made available;
2) non-medical testing facilities (e.g. facilities routinely testing animal products) performing specialised diagnostic testing. These facilities are considered by NATA on a case-by-case basis and aligned with the TGA IVD Regulations. Facilities performing this testing using In-house IVDs are subject to assessment against the NPAAC Requirements for the development and use of in-house in vitro diagnostic medical devices (IVDs).

Applicant and accredited facilities must comply with all relevant documents in the NATA Accreditation Criteria (NAC) package applicable to the activities covered, or proposed to be covered, by their scope of accreditation (refer to *NATA Procedures for Accreditation).*

The clause numbers in this document follow those of ISO/IEC 17025, however, as not all clauses require interpretation the numbering may not be consecutive.

5 Structural requirements

5.2 Facilities must be under the control of an appropriately qualified and experienced staff member. Membership of professional societies should be maintained where possible to keep abreast of contemporary industry knowledge and developments (e.g. Australian Institute of Food Science and Technology, Australian Institute of Occupational Hygienists, Australian Society for Microbiology, Royal Australian Chemical Institute, etc.).

Any testing performed away from the base facility (such as in field or mobile testing facilities) must be under adequate technical control.

6 Resource requirements

6.2 Personnel

6.2.3 Where staff are expected to work in areas, or at times other than those in which they would normally work (e.g. when relieving other staff or working on a weekend), a program of regular refresher training must be established and records retained. Staff who work only 'out-of-hours' must have regular contact with routine staff and in particular supervisory staff. A mechanism must be in place to ensure that staff who work outside of normal working hours are kept up to date with changes and decisions that occur during the normal working day (e.g. email or virtual platform chat function).

The time allocated must, however, be sufficient for the staff member to update all skills required for the out-of-hours service. Records of the above must be available to the assessment team and be sufficiently detailed to demonstrate compliance.

Staff with colour vision impairment may have difficulty performing some tests. Colour vision is, therefore, one of the issues that facility management must consider, when determining the suitability of staff to perform specific tests.

6.2.6 Staff authorising results must be approved on the basis of their demonstrated ability to evaluate the validity of the test results.

6.3 Facilities and environmental conditions

6.3.2 Specific requirements for facilities carrying out molecular testing including analysis of genetically modified materials are detailed in the *Specific Accreditation Criteria: ISO/IEC 17025 Application Document, Life Sciences - Annex, Facilities using nucleic acid detection techniques (including testing for genetically modified materials).*

6.3.5 When testing in the field, testing sites must be chosen to minimise the effects of environmental conditions and contamination.

6.4 Equipment

Microbiological culture collection management

Refer to *General Accreditation Criteria: Maintenance of Microbiological Reference Culture Collections (MRCC)* for criteria covering the selection, maintenance, and use of microbiological cultures.

6.4.4

Consumables

Items must be stored in accordance with the manufacturer's recommendations and should be discarded on the expiry date. Consumables used beyond the manufacturer's expiry date must be validated routinely prior to each use. The onus is on the facility to prove that reagents used beyond the manufacturers recommended date do not adversely affect the outcome of the test.

Kits

QC must be performed on microbiological identification kits (e.g. API) using relevant test organisms from a recognised type culture. QC must be performed on commencing the use of a batch of kits with a new production lot number, using one or more of the strains of organism recommended by the manufacturer (preferably in rotation).

Microbiological Media

Refer to *General Accreditation Criteria: Media Preparation and Quality Control* for requirements related to media preparation and quality control.

Virology

The Australian Society for Microbiology recommends that commercial suppliers of viral culture media be NATA accredited. Facilities should therefore purchase culture media from NATA accredited suppliers.

6.4.8 The shelf lives of consumables must be established and documented where these may affect the validity of results.

6.4.13 Details of standard solutions and reagents, both prepared in-house and purchased, must be recorded. These records must include:

- all raw data relating to preparation including ingredients and quantities used (weights, volumes, etc.);
- date of preparation;
- identity of preparer;
- date of expiry;
- manufacturer and manufacturer's batch number (where applicable);
- results of standardisation including standard curves (where applicable);
- safety precautions and/or handling instructions, where relevant.

Further, reagents must be labelled appropriately.

Each batch of purchased standard solution and or reagent must be verified before use and records retained.

Records must be kept of the date of receipt and date of initial use of consumables including diagnostic reagents.

7 Process Requirements

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 A facility may seek accreditation for an "open" scope of accreditation, where a descriptor for a collective group of analytes, such as "organochlorine pesticides", rather than specific individual analytes such as "dichlorvos, dieldrin, and endosulfan" is included under the "Determinant" column in the scope of accreditation.

An open scope of accreditation allows a facility to claim accreditation for new analytes, falling within the collective group descriptor, without the need for seeking an extension to its scope of accreditation for the specific analyte.

Accreditation of an open scope of accreditation places more responsibility on the facility to demonstrate that valid, fit-for-purpose methods are performed competently. This, however, does not mean that a facility can undertake any test requested by a customer and claim accreditation. The bounds within which the scope of accreditation is open must be clearly defined and supported by established procedures.

Documented procedures must include as a minimum:

- how the facility applies existing techniques covered by its scope of accreditation to a collective group of analytes;
- what matrices and analytes may be covered, including the maintenance of a current listing of these;
- how methods are selected and modified as necessary;
- the verification and/or validation processes necessary for any modifications required to existing methods to test for additional analytes;
- define the appropriate reference standards or reference materials to be used.

Review of the procedures and supporting records will be performed as part of each assessment. The facility will also be expected to demonstrate its competence to analyse specific examples of analytes covered by the collective descriptor.

An open scope of accreditation is only available to facilities with a sound assessment history.

Where concerns are raised with a facility's competence to implement and maintain an open scope of accreditation, reports issued covering results under the open scope of accreditation may be required to be withdrawn and affected customers to be advised. Further, the eligibility of the facility to hold an open scope of accreditation may be reviewed.

An open scope of accreditation is not available when a new technique is adopted not already covered by the "Service" applicable to the open scope of accreditation (e.g. introduction of ICP-MS for calcium when accreditation is held for AAS).

7.2.1.5 Published test methods that do not include precision data (i.e. working range, detection limit, reproducibility and measurement uncertainty) must be supplemented by the facility based on its own test data.

7.2.2 Validation of methods

7.2.2.1 Procedures for method validation must include details of the statistical analyses to be applied for determining precision data.

In developing and validating test methods, as a minimum, the following parameters must be considered:

- selectivity;
- linearity of response;
- sensitivity;
- accuracy (trueness and precision);
- limit of detection and limit of quantitation;
- range;
- ruggedness;
- measurement uncertainty of results;
- traceability of results.

7.3 Sampling

7.3.1 Where sample collection is outside the control of the facility, the collectors should be informed of the facility's collection requirements. For example:

- containers/tubes required for each test;
- sampling procedure to follow;
- amount of sample required;
- labelling requirements;
- recording the date and time of sampling;
- sample storage requirements (e.g. room temperature vs refrigeration);
- sample transport requirements;
- requirements with respect to request forms;
- preservation requirements;
- provision of other relevant information.

Sample containers must be leak-proof and impervious to contamination. It may be necessary to test containers before use to ensure freedom from contamination.

7.4 Handling of test and calibration items

7.4.2 Sample containers must be securely and legibly labelled on the body (of the container) and the cap / lid. Labelling only caps / lids is not acceptable because of the risk of wrongly replacing these.

7.6 Evaluation of measurement uncertainty

7.6.3 Measurement uncertainty (MU) associated with the measurand must be determined:

- for tests where a quantitative determination is reported, including the most probable number technique;
- for tests where a numerical value is reported as a qualitative result (e.g. ELISA assays with a 'cut off' value);
- where the numerical result is reported as detected or not detected.

Where results of tests are not numerically derived (i.e. qualitative), estimates of uncertainty are not required. This should not however preclude the facility from developing an understanding of the components that contribute significantly to the variability of results of such tests.

7.7 Assuring the validity of results

7.7.1

Internal quality control procedures shall include:

- use of control material (positive and negative as appropriate):
  - where bacteria are tested, positive controls (e.g. target organisms or analyte) must be run for each method in parallel with each batch of samples;
  - the level of the inoculum of positive controls must be sufficient to adequately replicate low level contamination and the limit of detection of the tests.

  Note: The availability of manufacturers' kit controls does not preclude the use of other positive controls.
- media quality control (see clause 6.4.4);
- instrument calibration and maintenance;
- implementation of criteria for rejecting questionable results;
- implementation of predetermined control criteria for infrequently performed tests (e.g. use of suitable reference materials with each batch of samples).

7.8 Reporting of results

7.8.1 General

7.8.1.2 When required to report a 'total' result, for example 'total polynuclear aromatic hydrocarbons', 'total microcystins' or 'total phenols', the facility must ensure that:

- a scientifically valid method is used to calculate the total result;
- the 'total' is clearly defined in the test method;
- the way the total is calculated, in particular the value attributed to compounds included in the total that are measured at less than their limit of quantitation, is clearly described in the test method;
- the test report clearly defines 'total' in the context of the reported result (this information may be provided by reference to a standard method); and
- the customer fully understands all aspects of the test result.

When reporting the results for organic analytes, for which no reference material is available and the result is reported on the basis of a GC-MS database match, the following apply:

- the match must be done on the basis of full scan mode only and the report must cite the database used, the library ranking (in-house, commercial (specify)), and the percentage match;
- quantitation must not be reported on the basis of a database match.

7.8.3 Specific requirements for test reports

7.8.3.1 In cases where a quantitative test consistently returns results at or below the limit of detection (e.g. <1/10mLs) the result is to be treated as a qualitative result and MU is therefore not required to be reported.

7.8.7 Reporting opinions and interpretations

7.8.7.1 Where opinions and interpretations are included in reports, they must be technically and professionally valid and traceable to authoritative references.

Note: Authoritative references include guidelines and standards set by government bodies such as the NEPC and NHRMC.

Facilities may include comments and/or interpretation of results in a separate document that is clearly linked to the corresponding report (e.g. by report number).

Facilities engaged in testing performed on human specimens shall not include any opinions or interpretations on test reports for the purposes of diagnosis, treatment or monitoring of a patient. Where opinions or interpretations are to be reported, accreditation against ISO 15189 is to be sought.

Note: Testing on human specimens may be subject to the Therapeutic Goods Administration (TGA) In-Vitro Diagnostic (IVD) medical device Framework and assessment against the National Pathology Accreditation Advisory Council (NPAAC) *Requirements for the Development and Use of In-house In Vitro Diagnostic Medical Devices (IVDs)*.

References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

Standards

ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories

NATA Publications

Applicable NATA Accreditation Criteria (NAC) package(s) (Agribusiness; Environment; Food & Beverage; Healthcare, Pharmaceutical & Media Products; Human Testing for Workplace and/or Community Screening)

General Accreditation Criteria	Proficiency Testing Policy
General Accreditation Criteria	Media Preparation and Quality Control
General Accreditation Criteria	Maintenance of Microbiological Reference Culture Collections (MRCC)
Specific Accreditation Criteria	ISO/IEC 17025 Application Document, Life Sciences - Annex, Facilities using nucleic acid detection techniques (including for genetically modified materials)

Other Publications

National Pathology Accreditation Advisory Council (NPAAC), *Requirements for the Development and Use of In-house In Vitro Diagnostic Medical Devices (IVDs)*

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
Title page	Inclusion of Human Pathology testing in exceptional circumstances
Purpose	Inclusion of exceptional circumstances for Human Pathology testing